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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------|------------------|
| 09/687,575  | 10/13/2000  | Rima Kaddurah-Daouk  | AVZ-007CP3           | 9336             |
| 959   | 7590        | 11/14/2005           | EXAMINER             |                  |
| LAHIVE & COCKFIELD, LLP.<br>28 STATE STREET<br>BOSTON, MA 02109 |             |                      | COVINGTON, RAYMOND K |                  |
|   |             |                      | ART UNIT             | PAPER NUMBER     |
|   |             |                      | 1625                 |                  |

DATE MAILED: 11/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/687,575

Applicant(s)

KADDURAH-DAOUK ET AL.

Examiner

Raymond Covington

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-4,6-8,10-18,34-39,64-74,76-82,86-89,91-96,98-104,108,113-118,120-126 and 130-132 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

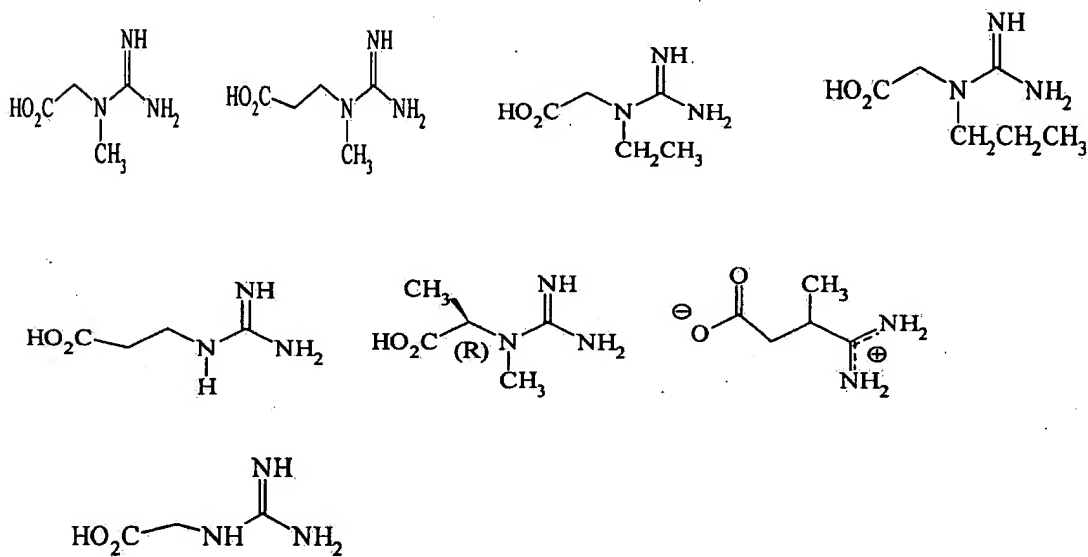
### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C.

121:

Restriction to one of the following inventions is required under 35 U.S.C. 121;

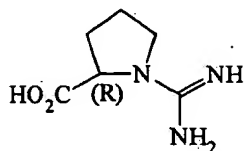
1. Claims 1-4, 6-8, 10-12, 17, 18 in part, drawn to a method of increasing ATP production using creatine compounds of the formula



with non-cyclic non-phosphate containing substituents, including its pharmaceutical salts and an CoQ, spin trap, carnitine, pyruvate, lutein, vitamin E or vinpocetine ATP enhancing agent, classified in class 514 and multiple subclasses. This group may be

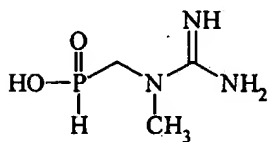
subjected to further restriction. A single disclosed species is requested for search purposes.

2. Claims 1-4, 6-8, 10-12, 17, 18, in part, drawn to a method of increasing ATP production using creatine compounds of the formula



with 5 member 1 nitrogen N-heterocyclic containing substituents, including its pharmaceutical salts and an CoQ, spin trap, carnitine, pyruvate, lutein, vitamin E or vinpocetine ATP enhancing agent , classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

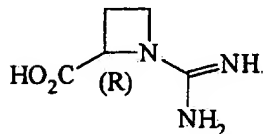
3. Claims 1-4, 6-8, 10-12, 17, 18 in part, drawn to a method of increasing ATP production using creatine compounds of the formula



with non-cyclic phosphate containing substituents, including its pharmaceutical salts and an CoQ, spin trap, carnitine, pyruvate, lutein, vitamin E or vinpocetine ATP enhancing agent ,

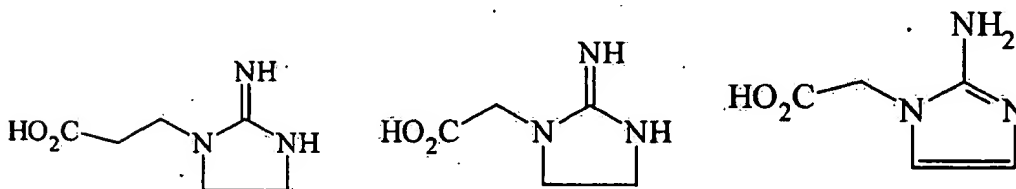
classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

- 4 Claims 1-4, 6-8, 10-12, 17, 18 in part, drawn to a method of increasing ATP production using creatine compounds of the formula



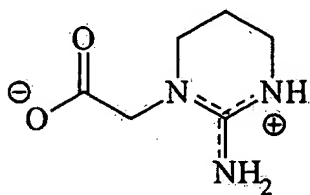
with 4-member heterocyclic containing substituents, including its pharmaceutical salts and an CoQ, spin trap, carnitine, pyruvate, lutein, vitamin E or vinpocetine ATP enhancing agent , classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

- 5 Claims 1-4, 6-8, 10-12, 17, 18 in part, drawn to a method of increasing ATP production using creatine compounds of the formula



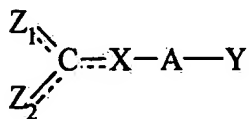
with 5 member 2 nitrogen N-heterocyclic containing substituents, including its pharmaceutical salts and an CoQ, spin trap, carnitine, pyruvate, lutein, vitamin E or vinpocetine ATP enhancing agent , classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

- 6 Claims 1-4, 6-8, 10-12, 17, 18 in part, drawn to a method of increasing ATP production using creatine compounds of the formula



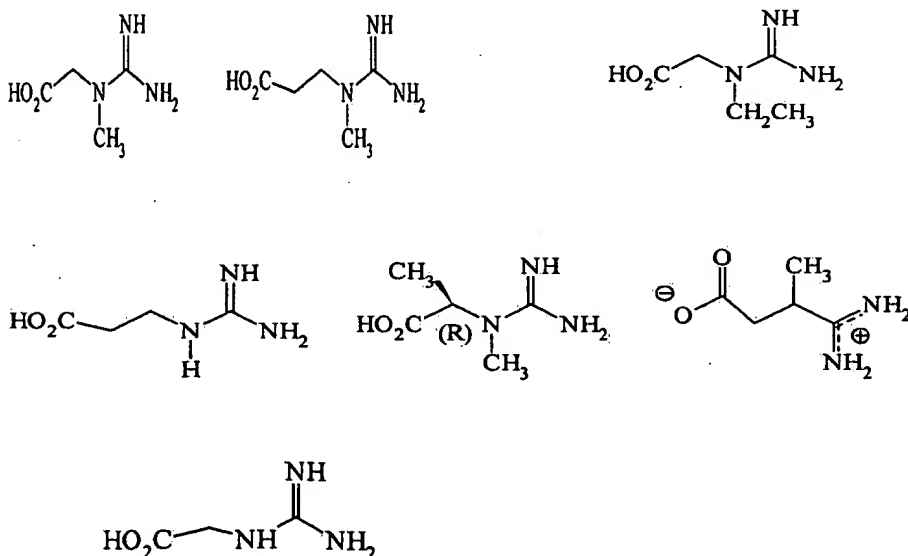
with 6 member 2 nitrogen N-heterocyclic containing substituents, including its pharmaceutical salts and an CoQ, spin trap, carnitine, pyruvate, lutein, vitamin E or vinpocetine ATP enhancing agent , classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

- 7 Claims 1-4, 6-8, 10-12, 17, 18 in part, drawn to a method of increasing ATP production using creatine compounds of the formula



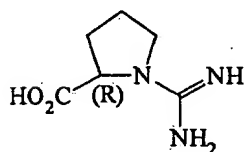
not otherwise provided for in groups I-IV above, classified in multiple classes and subclasses, including its pharmaceutical salts and an CoQ, spin trap, carnitine, pyruvate, lutein, vitamin E or vinpocetine ATP enhancing agent, classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

8. Claims 34-39 in part, drawn to a method of protecting a nervous system against oxidative damage using creatine compounds of the formula



with non-cyclic non- phosphate containing substituents, including its pharmaceutical salts and an CoQ, spin trap, carnitine, pyruvate, lutein, vitamin E alpha-omega fatty acids, BHP, alpha-lipoate, thiocctic acid, 1,2-dithiolane-3-pentanoic acid, 1,2-dithiolane-3 valeric acid, and 6,8-dithiooctanoic acid or vinpocetine ATP enhancing agent , classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

9. Claims 34-39, in part, drawn to protecting a nervous system against oxidative damage using creatine compounds of the formula

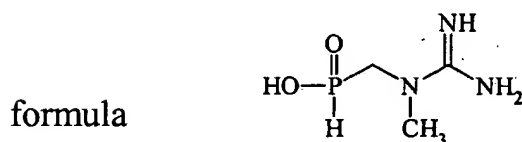


with 5 member 1 nitrogen N-heterocyclic containing substituents, including its pharmaceutical salts and an CoQ, spin trap, carnitine, pyruvate, lutein, vitamin E alpha-omega fatty acids, BHP, alpha-lipoate, thiocctic acid, 1,2-dithiolane-3-pentanoic acid, 1,2-dithiolane-3 valeric acid, and 6,8-dithiooctanoic acid or vinpocetine ATP enhancing agent , classified in class 514 and multiple subclasses.



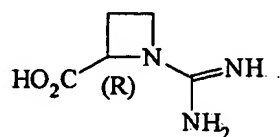
This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

10. Claims 34-39 in part, drawn to a method of protecting a nervous system against oxidative damage using creatine compounds of the



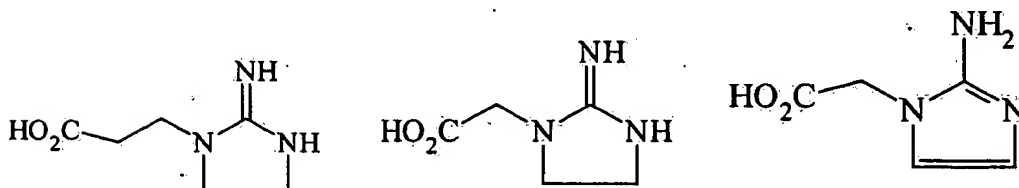
with non-cyclic phosphate containing substituents, including its pharmaceutical salts and an CoQ, spin trap, carnitine, pyruvate, lutein, vitamin E alpha-omega fatty acids, BHP, alpha-lipoate, thiocctic acid, 1,2-dithiolane-3-pentanoic acid, 1,2-dithiolane-3 valeric acid, and 6,8-dithiooctanoic acid or vinpocetine ATP enhancing agent , classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

- 11 Claims 34-39 in part, drawn to a method of protecting a nervous system against oxidative damage using creatine compounds of the formula



with 4 member heterocyclic containing substituents, including its pharmaceutical salts and an CoQ, spin trap, carnitine, pyruvate, lutein, vitamin E alpha-omega fatty acids, BHP, alpha-lipoate, thiocctic acid, 1,2-dithiolane-3-pentanoic acid, 1,2-dithiolane-3 valeric acid, and 6,8-dithiooctanoic acid or vinpocetine ATP enhancing agent , classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

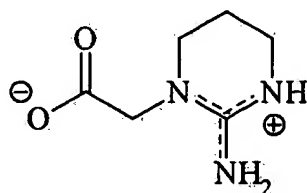
- 12 Claims 34-39 in part, drawn to a method of protecting a nervous system against oxidative damage using creatine compounds of the formula



with 5 member 2 nitrogen N-heterocyclic containing substituents, including its pharmaceutical salts and an CoQ, spin trap, carnitine, pyruvate, lutein, vitamin E alpha-omega fatty acids, BHP, alpha-

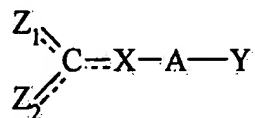
lipoate, thioctic acid, 1,2-dithiolane-3-pentanoic acid, 1,2-dithiolane-3 valeric acid, and 6,8-dithiooctanoic acid or vinpocetine ATP enhancing agent , classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

- 13 Claims 34-39 in part, drawn to a method of protecting a nervous system against oxidative damage using creatine compounds of the formula



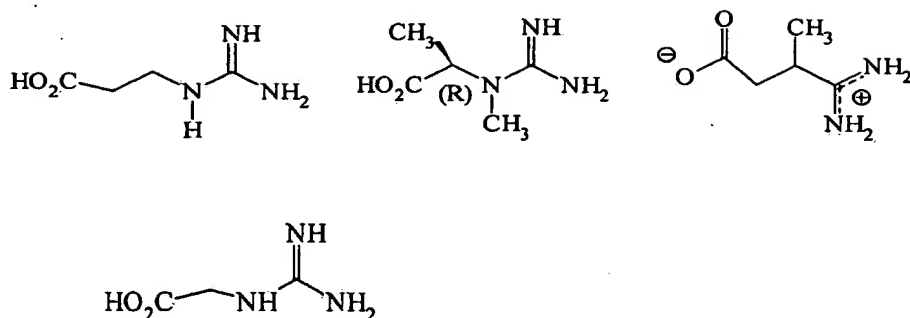
with 6 member 2 nitrogen N-heterocyclic containing substituents, including its pharmaceutical salts and an CoQ, spin trap, carnitine, pyruvate, lutein, vitamin E alpha-omega fatty acids, BHP, alpha-lipoate, thioctic acid, 1,2-dithiolane-3-pentanoic acid, 1,2-dithiolane-3 valeric acid, and 6,8-dithiooctanoic acid or vinpocetine ATP enhancing agent , classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

- 14 Claims 34-39 in part, drawn to a method of protecting a nervous system against oxidative damage using creatine compounds of the formula



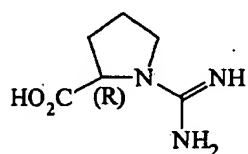
not otherwise provided for in groups I-IV above, classified in multiple classes and subclasses, including its pharmaceutical salts and an CoQ, spin trap, carnitine, pyruvate, lutein, vitamin E alpha-omega fatty acids, BHP, alpha-lipoate, thiocctic acid, 1,2-dithiolane-3-pentanoic acid, 1,2-dithiolane-3 valeric acid, and 6,8-dithiooctanoic acid or vinpocetine ATP enhancing agent, classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

15. Claims 64, 69-82 in part, drawn to a method of treating amyotrophic lateral sclerosis using creatine compounds of the formula



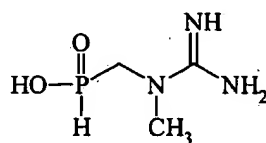
with non-cyclic non-phosphate containing substituents, including its pharmaceutical salts and an inhibitor of glutamate excitotoxicity, 2,3-dimethoxy-5-methyl-6-decaprenyl benzoquinone, nicotinamide, spin traps, growth factors, nitric oxide synthase inhibitors, cyclooxygenase 2 inhibitors, aspirin, ICE inhibitors, neuroimmunophilis, N-acetylcysteine, antioxidants, lipoic acid, cofactors, riboflavin, and CoQ10 neuroprotective agent, classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

16. Claims 64, 69-82, in part, drawn to a method of treating amyotrophic lateral sclerosis using creatine compounds of the formula



with 5 member 1 nitrogen N-heterocyclic containing substituents, including its pharmaceutical salts and a inhibitor of glutamate excitotoxicity, 2,3 dimethoxy-5-methyl-6-decaprenyl benoquinone, nicotinamide, spin traps, growth factors, nitric oxide synthase inhibitors, cyclooxygenase 2 inhibitors, aspirin, ICE inhibitors, neuroimmunophilis, N-acetylcysteine, antioxidants, lipoic acid, cofactors, riboflavin, and CoQ10 neuroprotective agent, classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

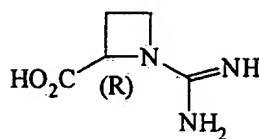
17. Claims 64, 69-82 in part, drawn to a method of treating amyotrophic lateral sclerosis using creatine compounds of the formula



with non-cyclic phosphate containing substituents, including its pharmaceutical salts and a inhibitor of glutamate excitotoxicity, 2,3 dimethoxy-5-methyl-6-decaprenyl benoquinone, nicotinamide, spin traps, growth factors, nitric oxide synthase inhibitors, cyclooxygenase

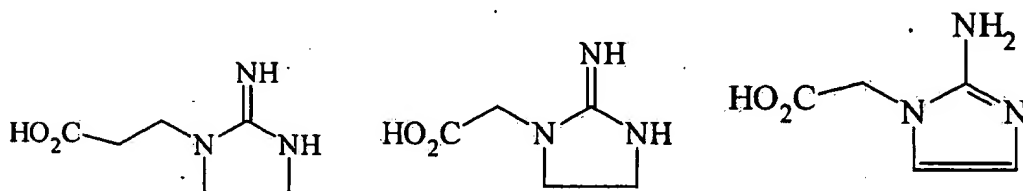
2 inhibitors, aspirin, ICE inhibitors, neuroimmunophilis, N-acetylcysteine, antioxidants, lipoic acid, cofactors, riboflavin, and CoQ10 neuroprotective agent, classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

- 18 Claims 64, 69-82 in part, drawn to a method of treating amyotrophic lateral sclerosis using creatine compounds of the formula



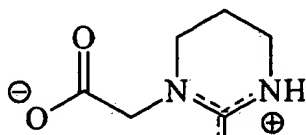
with 4 member heterocyclic containing substituents, including its pharmaceutical salts and a inhibitor of glutamate excitotoxicity, 2,3 dimethoxy-5-methyl-6-decaprenyl benoquinone, nicotinamide, spin traps, growth factors, nitric oxide synthase inhibitors, cyclooxygenase 2 inhibitors, aspirin, ICE inhibitors, neuroimmunophilis, N-acetylcysteine, antioxidants, lipoic acid, cofactors, riboflavin, and CoQ10 neuroprotective agent, classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

- 19 Claims 64, 69-82 in part, drawn to treating amyotrophic lateral sclerosis using creatine compounds of the formula



with 5 member 2 nitrogen N-heterocyclic containing substituents, including its pharmaceutical salts and a inhibitor of glutamate excitotoxicity, 2,3 dimethoxy-5-methyl-6-decaprenyl benoquinone, nicotinamide, spin traps, growth factors, nitric oxide synthase inhibitors, cyclooxygenase 2 inhibitors, aspirin, ICE inhibitors, neuroimmunophilis, N-acetylcysteine, antioxidants, lipoic acid, cofactors, riboflavin, and CoQ10 neuroprotective agent, classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

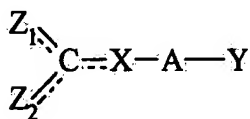
- 20 Claims 64, 69-82 in part, drawn to a method of treating amyotrophic lateral sclerosis using creatine compounds of the formula





with 6 member 2 nitrogen N-heterocyclic containing substituents, including its pharmaceutical salts and a inhibitor of glutamate excitotoxicity, 2,3 dimethoxy-5-methyl-6-decaprenyl benoquinone, nicotinamide, spin traps, growth factors, nitric oxide synthase inhibitors, cyclooxygenase 2 inhibitors, aspirin, ICE inhibitors, neuroimmunophilis, N-acetylcysteine, antioxidants, lipoic acid, cofactors, riboflavin, and CoQ10 neuroprotective agent , classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

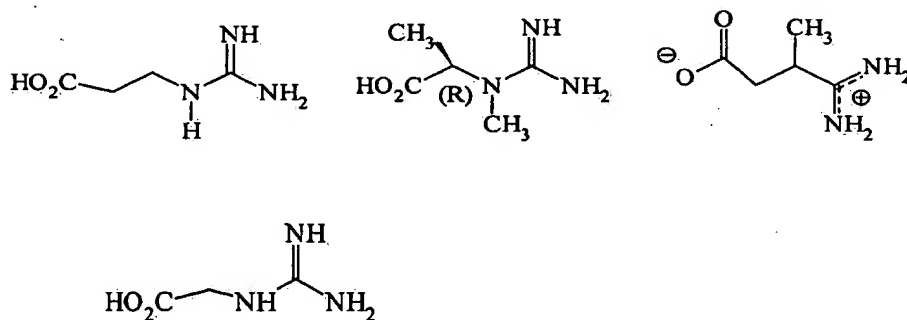
- 21 Claims 64, 69-82 in part, drawn to a method of treating amyotrophic lateral sclerosis using creatine compounds of the formula



not otherwise provided for in groups I-IV above, classified in multiple classes and subclasses, including its pharmaceutical salts and a inhibitor of glutamate excitotoxicity, 2,3 dimethoxy-5-methyl-6-decaprenyl benoquinone, nicotinamide, spin traps, growth factors, nitric oxide synthase inhibitors, cyclooxygenase 2 inhibitors, aspirin,

ICE inhibitors, neuroimmunophilis, N-acetylcysteine, antioxidants, lipoic acid, cofactors, riboflavin, and CoQ10 neuroprotective agent, classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

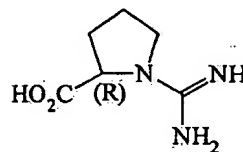
22. Claims 86, 91-96, 98-104, 108, 113-118, 120-126 in part, drawn to a method of treating Parkinson's disease or Huntington's disease using creatine compounds of the formula



with non-cyclic non-phosphate containing substituents, including its pharmaceutical salts and an inhibitor of glutamate excitotoxicity, 2,3-dimethoxy-5-methyl-6-decaprenyl benzoquinone, nicotinamide, spin

traps, growth factors, nitric oxide synthase inhibitors, cyclooxygenase 2 inhibitors, aspirin, ICE inhibitors, neuroimmunophilis, N-acetylcysteine, antioxidants, lipoic acid, cofactors, riboflavin, and CoQ10 neuroprotective agent, classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

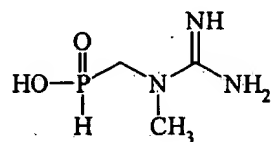
23. Claims 86, 91-96, 98-104, 108, 113-118, 120-126, in part, drawn to a method of treating Parkinson's disease or Huntington's disease using creatine compounds of the formula



with 5 member 1 nitrogen N-heterocyclic containing substituents, including its pharmaceutical salts and a inhibitor of glutamate excitotoxicity, 2,3 dimethoxy-5-methyl-6-decaprenyl benoquinone, nicotinamide, spin traps, growth factors, nitric oxide synthase inhibitors, cyclooxygenase 2 inhibitors, aspirin, ICE inhibitors, neuroimmunophilis, N-acetylcysteine, antioxidants, lipoic acid, cofactors, riboflavin, and CoQ10 neuroprotective agent, classified in

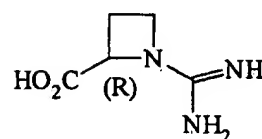
class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

24. Claims 86, 91-96, 98-104, 108, 113-118, 120-126 in part, drawn to a method of treating Parkinson's disease or Huntington's disease using creatine compounds of the formula

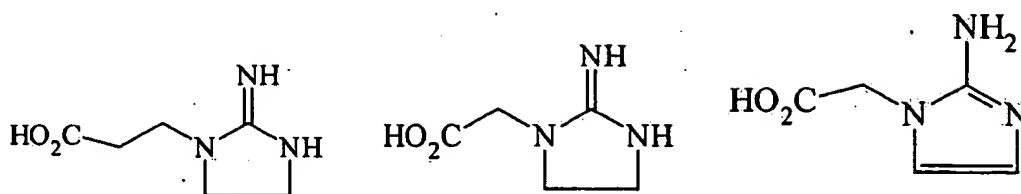


with non-cyclic phosphate containing substituents, including its pharmaceutical salts and a inhibitor of glutamate excitotoxicity, 2,3 dimethoxy-5-methyl-6-decaprenyl benoquinone, nicotinamide, spin traps, growth factors, nitric oxide synthase inhibitors, cyclooxygenase 2 inhibitors, aspirin, ICE inhibitors, neuroimmunophilis, N-acetylcysteine, antioxidants, lipoic acid, cofactors, riboflavin, and CoQ10 neuroprotective agent, classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

- 25 Claims 86, 91-96, 98-104, 108, 113-118, 120-126 in part, drawn to a method of treating Parkinson's disease or Huntington's disease using creatine compounds of the formula

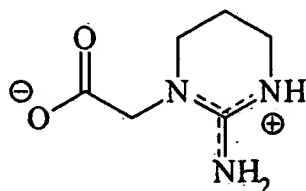


- with 4 member heterocyclic containing substituents, including its pharmaceutical salts and a inhibitor of glutamate excitotoxicity, 2,3 dimethoxy-5-methyl-6-decaprenyl benoquinone, nicotinamide, spin traps, growth factors, nitric oxide synthase inhibitors, cyclooxygenase 2 inhibitors, aspirin, ICE inhibitors, neuroimmunophilis, N-acetylcysteine, antioxidants, lipoic acid, cofactors, riboflavin, and CoQ10 neuroprotective agent, classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.
- 26 Claims 86, 91-96, 98-104, 108, 113-118, 120-126 in part, drawn to a method treating Parkinson's disease or Huntington's disease using creatine compounds of the formula



with 5 member 2 nitrogen N-heterocyclic containing substituents, including its pharmaceutical salts and a inhibitor of glutamate excitotoxicity, 2,3 dimethoxy-5-methyl-6-decaprenyl benoquinone, nicotinamide, spin traps, growth factors, nitric oxide synthase inhibitors, cyclooxygenase 2 inhibitors, aspirin, ICE inhibitors, neuroimmunophilis, N-acetylcysteine, antioxidants, lipoic acid, cofactors, riboflavin, and CoQ10 neuroprotective agent, classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes..

- 27 Claims 86, 91-96, 98-104, 108, 113-118, 120-126 in part, drawn to a method of treating Parkinson's disease or Huntington's disease using creatine compounds of the formula



with 6 member 2 nitrogen N-heterocyclic containing substituents, including its pharmaceutical salts and a inhibitor of glutamate excitotoxicity, 2,3 dimethoxy-5-methyl-6-decaprenyl benoquinone, nicotinamide, spin traps, growth factors, nitric oxide synthase inhibitors, cyclooxygenase 2 inhibitors, aspirin, ICE inhibitors, neuroimmunophilis, N-acetylcysteine, antioxidants, lipoic acid, cofactors, riboflavin, and CoQ10 neuroprotective agent , classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

- 28 Claims 86, 91-96, 98-104, 108, 113-118, 120-126 in part, drawn to a method of treating Parkinson's disease or Huntington's disease using creatine compounds of the formula
- $$\begin{array}{c} Z_1 \\ \diagdown \\ C \\ \diagup \\ Z_2 \end{array} = X - A - Y$$
- not otherwise provided for in groups I-IV above, classified in multiple classes and subclasses, including its pharmaceutical salts and a inhibitor of glutamate excitotoxicity, 2,3 dimethoxy-5-methyl-6-decaprenyl benoquinone, nicotinamide, spin traps, growth factors, nitric oxide synthase inhibitors, cyclooxygenase 2 inhibitors, aspirin, ICE inhibitors, neuroimmunophilis, N-acetylcysteine, antioxidants,

with 6 member 2 nitrogen N-heterocyclic containing substituents, including its pharmaceutical salts and a inhibitor of glutamate excitotoxicity, 2,3 dimethoxy-5-methyl-6-decaprenyl benoquinone, nicotinamide, spin traps, growth factors, nitric oxide synthase inhibitors, cyclooxygenase 2 inhibitors, aspirin, ICE inhibitors, neuroimmunophilis, N-acetylcysteine, antioxidants, lipoic acid, cofactors, riboflavin, and CoQ10 neuroprotective agent , classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

- 28 Claims 86, 91-96, 98-104, 108, 113-118, 120-126 in part, drawn to a method of treating Parkinson's disease or Huntington's disease using creatine compounds of the formula
- $$\begin{array}{c} Z_1 \\ \diagdown \\ C \\ \diagup \\ Z_2 \end{array} = X - A - Y$$
- not otherwise provided for in groups I-IV above, classified in multiple classes and subclasses, including its pharmaceutical salts and a inhibitor of glutamate excitotoxicity, 2,3 dimethoxy-5-methyl-6-decaprenyl benoquinone, nicotinamide, spin traps, growth factors, nitric oxide synthase inhibitors, cyclooxygenase 2 inhibitors, aspirin, ICE inhibitors, neuroimmunophilis, N-acetylcysteine, antioxidants,



lipoic acid, cofactors, riboflavin, and CoQ10 neuroprotective agent, classified in class 514 and multiple subclasses. This group may be subjected to further restriction. A single disclosed species is requested for search purposes.

- 29 Claim 130-132 are in part, is drawn to a pharmaceutical composition of the formula in the Groups set forth herein above and a pharmaceutically acceptable carrier, classified in multiple classes and subclasses. This group may be subjected to further restriction.

The inventions are distinct, each from the other because of the following reasons:

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case:

Inventions 1-28 are unrelated and different inventions since each one of the said groups are drawn methods using compounds having a particular core per groups the compounds embraced in each group have its own reactivity, structure and variable groups and a reference anticipating or suggesting a given group

cannot be used to reject any of the others under the meaning of 35 USC 102 or 35 USC 103.

Inventions 1-28 are unrelated because each one of the said groups are drawn to methods treating different unrelated diseases and conditions having no nexus using different sets of compounds embraced by different groups already shown to be a separate and distinct inventions. For example, hair dying, increasing ATP, protecting a nervous system against oxidative damage, treating tuberculosis, treating amyotrophic lateral sclerosis, food coloring, Parkinson's disease and dietary supplement. Note, for example CA 61-94613, CA 61-87267.

Inventions 29, drawn to products and 1-28, drawn to process of use, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case products as claimed can be used in a materially different process such as hair dying, treating tuberculosis, food coloring, and dietary supplement.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are patentably **independent and distinct** for the reasons given above and the **search required would be burdensome**, restriction for examination purposes as indicated is proper.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species for the purpose of examination.

It is also suggested that the structural formula of the creatine compound used in the elected process or composition also be given.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process of use claims will be withdrawn, and the rejoined claims will be fully examined for patentability in accordance with 37 CFR 1.104.

Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

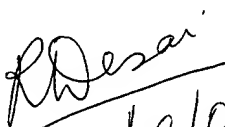
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (571) 272-0681. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RKC

Raymond Covington  
Examiner  
Art Unit 1625

  
11/19/05

Continuation of Disposition of Claims: Claims pending in the application are 1-4,6-8,10-18,34-39,64-74,76-82,86-89,91-96,98-104,108,113-118,120-126 and 130-132.